

10/500207

PATENT COOPERATION TREATY

PCT/JP2002/013650



Translation

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

28 JUN 2004

Applicant's or agent's file reference 1442	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2002/013650	International filing date (day/month/year) 26 December 2002 (26.12.2002)	Priority date (day/month/year) 28 December 2001 (28.12.2001)
International Patent Classification (IPC) or national classification and IPC A61K 39/395, A61P 19/02, G01N 33/564		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand 25 July 2003 (25.07.2003)	Date of completion of this report 06 February 2004 (06.02.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2002/013650

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP 02/13650

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-51	YES
	Claims		NO
Inventive step (IS)	Claims	1-51	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-51	YES
	Claims		NO

## 2. Citations and explanations

Document 1: Yukiko Kurihara et al., "Cooperation of endothelin-1 and FGF8 in Meckel's cartilage formation", Development, Growth & Differentiation, 2001, Vol. 43, Supplement, p. S109

Document 2: Craig A. Praul et al., "Effect of fibroblast growth factors 1, 2, 4, 5, 6, 7, 8, 9 and 10 on avian chondrocyte proliferation", Journal of Cellular Biochemistry, October 2001, Vol. 84, No. 2, pp. 359-366

Document 3: EP 799835 A2 (Kyowa Hakko Kogyo Co., Ltd.), 8 October 1997

Document 4: WO 00/62809 A1 (Kyowa Hakko Kogyo Co., Ltd.), 26 October 2000

Document 5: EP 882794 A2 (Kyowa Hakko Kogyo Co., Ltd.), 9 December 1998

Document 6: JP 2001-46066 A (Kyowa Hakko Kogyo Co., Ltd.), 20 February 2001

## Novelty and inventive step

Document 1 discloses the fact that expression of Sox9, which contributes to joint formation, is suppressed by an anti-FGF-8 antibody.

Document 2 discloses the fact that FGF-8 causes

proliferation of chondrocytes.

Document 3 discloses monoclonal antibodies which react specifically with FGF-8 and inhibit the activity thereof, and indicates the use of such antibodies in the treatment of tumours.

Document 4 discloses the fact that tumour growth is suppressed by an anti-FGF-8 antibody.

Documents 5 and 6 disclose humanized antibodies.

However, none of the documents above discloses or suggests the possibility of treating arthritis with an anti-FGF-8 antibody.

Therefore, none of the documents cited in the international search report takes away the novelty and inventive step of the inventions set forth in claims 1-51.